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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,244	MILLER, WINFRIED	
	Examiner	Art Unit	
	KADE ARIANI	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,28-33 and 35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25, 28-33, and 35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments filed on October 10, 2008, has been received and entered.

New Claims 38-40 have been added.

Claims 1-25, 28-33 and 35-40 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 11 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdraw due to Applicants amendments to the claims filed on 10/10/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-10, 12-17, 23, 25, 28-31, 36 and 37 under 35 U.S.C. 102(b) as being anticipated by Greenberg (US Patent No. 5, 569,458), is withdrawn due to Applicants amendments filed on 10/10/2008.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Greenberg (US Patent No. 5, 569,458).

Claim 24 is drawn to a food product for food supplementation comprising one or more plant protease and/or one or more animal protease, antioxidants comprising vitamins having antioxidant activity, and selenium-containing substances, one or more flavonoids and/or one or more flavonoid-containing substances, and optionally one or more amino acids, one or more polysaccharides, or combinations thereof, wherein said food product contributes to a balanced diet, strengthens the immune defenses.

Greenberg discloses a dietary supplement comprising bromelain, papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), selenium-containing substances (selenium amino acid complex), citrus bioflavonoid complex, amino acids (L-glycine), and mucopolysaccharides (polysaccharides) (column 2 lines 64, column 3 lines 1-30 and 33-46). Greenberg further disclose the composition strengthens the immune system (column 5 lines 26-28).

Greenberg therefore clearly anticipate the claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25, 28-33 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Murray, MT (2001, Proteolytic enzymes in Cancer Therapy, pages 1-2) and further in view of Manthey et al. (Current Medicinal Chemistry, 2001, Vol.8, p.135-153) and further in view of Rayman, M. P. (previously cited, The Lancet, 2000, Vol. 356, p. 233-241) and further in view of Vetvicka et al. (JANA, 2002, Vol. 5, No.2, p.5-9) and further in view of Ochao et al. (Journal of Parenteral & Enteral Nutrition, 2001, Vol. 25, No. 1, p.23-29) and further in view of Birt et al. (Pharmacology & Therapeutics, 2001, Vol. 90, p.157-177) and further in view of Jensen et al. (J. Nutr., 1999, Vol. 129, p.1355-1360).

Claims 1-23, 25, 28-33 and 35-40 are drawn to a composition comprising one or more plant protease and/or animal protease, wherein said one or more plant protease and/or animal protease have a total concentration of 20% to 60% by weight of active constituents in the composition, antioxidants comprising vitamins having antioxidant activity, and selenium-containing substance, one or more flavonoids and/or one or more flavonoid-containing substances, wherein one or more flavonoid-containing substances

have a total concentration of 10% to 50% by weight of active constituents in the composition, and optionally one or more amino acids, one or more polysaccharides or combinations thereof, one or more amino acids, one or more polysaccharides, one or more polyphenols, plant proteases is/are bromelain, and papain, animal proteases is/are trypsin or chymotrypsin, vitamins are selected from vitamin A, C and E or the esters of vitamin A, and E, flavonoids comprise rutin, flavonoid-containing substances is citrus flavonoids, the composition further comprises coenzyme Q-10, the composition further comprises carotenoids, carotenoids are carotene, amino acid is glycine, wherein the selenium-containing substance having antioxidant activity is sodium selenite present in a concentration of 0.01 to 0.1% by weight, a medicament that strengthens the immune response, a dietetic treatment comprising administering to a patient in need for such treatment the composition of claim 1, said administration strengthens the immune response, method to regulate the immune system and to treat inflammatory disorders.

Greenberg teaches a composition (a dietary supplement) comprising bromelain (minimum 2500 m.c.u) (column 4 line 57), papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), vitamin E succinate, 69.2 microgram selenium amino acid complex or chelates (selenium-containing substances), proanthocyanidins (also known as OPC, grape seed flavonoid, are polyphenol and a flavonol), citrus bioflavonoid complex, rutin (a polyphenol), amino acids including L-glycine, polysaccharides (mucopolysaccharides), coenzyme Q-10, β-carotene (carotenoid) (column 2 lines 64, column 3 lines 1-30 and 33-46). Greenberg teaches at least one of digestive enzyme together with the pH balancing substance making up not more than

approximately 10% of the weight of the nutrition formulation (column 6 claim 1 lines 45-56). Greenberg further teaches the composition strengthens the immune system (column 5 lines 26-28). Greenberg teaches the formulation contain 34.6 mg citrus bioflavonoid (column 2 lines 58-59, column 3 -continued Table line 14). Greenberg also teaches a method comprising administering the dietary supplement to a patient (one capsule 3 times daily for adults) (column 3 lines 49-50).

Greenberg does not teach one or more protease have a total concentration of 20% to 60% by weight of active constituents in the composition, and flavonoids have a total concentration of 10% to 50% by weight of active constituents, carotenoid is lycopene, vitamin E acetate, amino acid is L-arginine, polysaccharide is β-glucan, quercetin from onion powder, the selenium-containing substance is sodium selenite in a concentration of 0.01 to 0.1% by weight. However, Murray teaches a composition comprising 47.4% pancreatin (trypsin and chymotrypsin, 200mg/422mg), papain 28.5% (120mg/422mg), and 12 % bromelain (50mg/422 mg). (Weight percent calculated using the total weight of the active ingredient is equal to 200+120+52+50 =422) (page 2 2nd column ingredients lines 6-9). Murray also teaches because the animal and vegetarian-derived enzymes have slightly different effects using the combination of the enzymes would provide maximum benefit (p.2. 1st column 1st paragraph lines 1-4).

Moreover, Manthey et al. teach anti-inflammatory properties of a composition comprising 10% of a flavonoid, due to inhibition of the synthesis of pro-inflammatory mediators of immune and inflammatory responses (p.138, 1st column 2nd paragraph).

Manthey et al. teach flavonoids modulate inflammation and immune responses (p.138, 2nd column 3rd paragraph).

Furthermore, Rayman teaches supplementation of selenium as sodium selenite, and supplementation of 200 µg selenium per day has immunoenhancing effects and additionally cells of the immune system may have an important functional need for selenium (p.234 1st column 2nd to 4th paragraphs). Rayman teaches because of the variation between individuals in the extent of the response to supplementation the requirements will differ between individuals in the same population (p.239 1st column 1st paragraph). Rayman teaches in sensitive individuals the maximum dietary intake may be as low as 600 µg per day, and it would be prudent to restrict adult intake from all sources to an upper limit of 400 to 450 µg/day as recommended by several expert panels (p.240 1st column 2nd paragraph lines 8-12).Therefore, a person of ordinary skill in the art at the time the invention was made would have realized that the amount of selenium (sodium selenite) supplementation would have depend on the individual's needs, diet, and the amount to be added to a dietary composition could have been calculated according to the recommended dose.

Furthermore, as indicated in MPEP, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which

was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)".

Even furthermore, Vetvicka et al. teach β-glucans, exhibit immunostimulating properties, including antibacterial and anti-tumor activities. Vetvicka et al. teach the results provide preclinical evidence for the beneficial effects of orally-administered β-glucans (Abstract, Introduction p.5, 1st column lines 1-2 and 2nd column 1st paragraph). Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to use polysaccharide β-glucan in an immunoenhancing composition.

Moreover, Ochao et al. teach dietary L-arginine enhance and stimulate cellular immune response (Abstract, p.24, 1st column 2nd paragraph). Thus, a person of ordinary skill in the art at the time the invention was made could have been motivated to use L-arginine in an immunoenhancing composition.

Further motivation to use flavonoid quercetin from onion (no citrus source) is in Birt et al. who teach flavonoids have many biological properties including the ability to regulate and enhance host immune function (p.171 2nd column 3rd paragraph). Birt et al.

further teach studies shows that adsorption of quercetin to be 3 fold greater (50% of ingested dose) after ingestion of quercetin predominantly in the glycosodic form from onions (p.165 2nd column 2nd paragraph lines 6-10). It must be noted that quercetin is also found in citrus fruits. Birt et al. also teach carotenoid and antioxidant lycopene (p.159, 2nd column 3rd paragraph).

Even further motivation to use antioxidant vitamin E acetate instead of vitamin E succinate as taught by Greenberg is in Jensen et al. who teach vitamin E acetate is a better vitamin E source because of higher efficiency of absorption (see Abstract).

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made could have been motivated to modify the concentration of animal and/or plant proteases and flavonoids in the composition as taught by Greenberg according to the teachings of Murray and Manthey et al. with predictable results of providing a composition with improved immune strengthening properties.

Moreover, a person of ordinary skill in the art at the time the invention was made could have been motivated to use the teachings of Rayman and use selenium as sodium selenite in the composition of Greenberg with predictable results of providing a composition with improved immune strengthening properties. The claim composition would have been obvious because substitution of one known form of selenium, in this case sodium selenite, for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Also, a person of ordinary skill in the art at the time the invention was made could have been motivated to substitute vitamin

E succinate in the Greenberg composition with vitamin E acetate as taught by Jensen et al. with predictable results of increasing the efficiency of vitamin E absorption.

Accordingly, a person of ordinary skill in the art at the time the invention was made could have been motivated to modify the composition as taught by Greenberg by adding polysaccharide β-glucan, amino acid L-arginine, flavonoid quercetin from onion, and antioxidant lycopene as taught by Vetvicka et al., Ochao et al., and Brit et al. with predictable results of providing a composition with improved immune strengthening and antioxidant properties. The motivation would be their immunostimulating and antioxidant properties. In turn, because the composition as claimed has health enhancing and immunoenhancing properties predicted by the prior art, it would have been obvious to make the claimed combination.

Applicant is directed to pages 12-13 of KSR v Teleflex (500 US ___ 2007) " ...the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

Response to Arguments

Applicant's arguments filed 10/10/2008 have been fully considered but they are not persuasive.

In response to applicant's argument that "Claim 24 is now in independent form and is directed to a food product for food supplementation, and Greenberg is directed to a formulation contained in capsules, and the claimed food product are separate from the composition as described in pages 19 and 20 of the disclosure", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use then it meets the claim.

In this case, Greenberg teaches the invention is created by a cold press method for granulating the ingredients into an ultrafine uncompressed powder which is then encapsulated. This system eliminates the problems found in the creation of standard supplement (namely high pressure and heat) that damages the quality and effectiveness of the nutrients (column 6 lines 13-19). Greenberg also teaches the instant formulation contains no yeast, soy, corn, dairy products, salt, sugar, artificial coloring, preservatives or flavoring. Greenberg also teaches the supplement is created without great pressure, heat, without additives, binders or other substances that decrease the effectiveness of the nutrients (column 3 lines 48-55).

Therefore, because encapsulating the composition comprising of powder ingredients in a capsule as taught by Greenberg does not result in a structural difference between the claimed invention and the prior art composition and Greenberg

composition is capable of providing a balanced diet and to strengthens the immune system. Thus, Greenberg meets the claim.

Moreover, specification page 19 lines 21-26, disclose "the compositions of the invention can be prepared by simply mixing the active constituents and are then present in the form of a powder. They may comprise exclusively the indicated active substances or comprise the latter in addition to conventional excipients".

Applicant argues that the combination of the cited references would have given the person of ordinary skill in the art no reason to pursue the invention as presently claimed.

However, as mentioned immediately above, all the claimed elements in the claimed composition were known in the prior art and a person of ordinary skill in the art could have combined the known elements as claimed with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. As indicated in MPEP "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651